Clinical study to evaluate efficacy of Arshahar in the management of Arsha w. s. r. to hemorrhoids.

Pathak Santosh*1, Sonambekar Vinay2, Yogesh sharma3

1. Assistant Professor: drsantoshsp@gmail.com
2. Professor & HOD: sonambekar.chinmay@gmail.com
3. P. G. Scholar

Shalya Tantra Dept., A.S.S Ayurved Mahavidyalaya, Nasik, Maharashtra, India 422003

*Corresponding author: 8770867132; Email: yogeshsharma281680@gmail.com

ABSTRACT

Arsha (hemorrhoids) is engorgement of the hemorrhoidal venous plexus, characterized by bleeding per rectum, constipation, pain, prolapse and discharge. The earliest reference of Arsha is available in Acharya Charaka, Sushruta and Kashyap Samhita. In modern point of view, it can be correlated with Haemorrhoids. In this study total 10 patients of Arsha having signs and symptoms of same, selected from Arogyashala Rugnalaya OPD of Shalyatantra Department. The patients were treated with prepared “Arshahar malam” to be applied locally for twise a day upto 10 days. The reference of Arshahar malam taken from various texts of Ayurvedic samhitas. It contains Nagkeshar, Lodhra, Nirgundi, lajjalu, Bheenseni Karpoor, Yasad Bhama And Tila Taila in appropriate proportion. All these drugs have property to subside the different symptoms belongs to Arsha. The combind effect of all these drugs are seen in this study.

Assessment was done on the basis of criteria such as bleeding, shotha according to grade of pile mass, and itching. On observation, result showed reduction of bleeding, shotha, and itching with advantages like affordable cost-effective and more acceptable to different categories of people, etc. were recorded in the Arshahar malam-treated group. No any complication seen in patients during follow up periods.

Key words: Arsha, Arshahar malam, hemorrhoids

INTRODUCTION

In the quest to find a quality life in 21st century, we often unknowingly host a number of diseases. Over the years, It is manifested due to improper diet, prolonged standing and faulty habits of defecation causing derangement of Tridosha, mainly Vata Dosha. These dosha cause agnimandhya. Vitiated Dosha localizes in Guda Vali, Pradhana Dhamani and Mansdhara Haemorrhoids, is an excessive distention of a vascular plexus which stretch the overlaying mucosa and anoderm, loosening their attachments to the muscle wall of anal canal. In the modern management of haemorrhoids Stool softeners, local
anesthetics, sitz bath and dietary changes advised do help in treating the haemorrhoids. Surgical interventions are also not required in majority of cases because. But in some cases with severe sign and symptom we advised surgical intervention. Some procedure are costly and some have post operative pain so we can not suggest surgery for all type of patient.

Ayurveda provide us the opportunity to treat Arsha with cost effective medication instead of surgical procedure. ‘Guda’ one of the Sadyapranahara marma, must be treated holistically to averse any future complications. Raktastrava and Gudasthani mamsa pradurabhava is the main complaint of the patient in the Arsha disease. Hence “Arshahar malam ” was chosen for the study. Arshahar malam is made up of lajjalu beeja, Nagkeshar, Lodhra, Nirgundi, Karpur(Bheemseni), Yasad Bhasma til taila And Siktha. Selection of drugs in ointment done accprding to their karma and prabhava which is explained by different achharya. Overall effect of these drugs observed in this study.

AIMS AND OBJECTIVES
To study the efficacy of Arshahar malam in the management of Arsha with special reference to Haemorrhoids.(1st, 2nd & 3rd digre)

MATERIALS AND METHODS
Total 10 patients of Arsha were selected from OPD and IPD of Shalyatantra Department with informed written consent of each patient. All the patients have completed the course of treatment with Arshahar malam for local application daily for 10 days. The symptoms like bleeding, shotha according to grade and itching recorded daily in the proforma designed especially for this study.

- **Inclusive criteria**
  1. Patient of both sex.
  2. Patients of age group 20 to 80yrs.
  3. Patient diagnosed as Arsha with sign and symptoms like- bleeding, shotha according to grade, burning, itching, H/o- constipation, rectal bleeding.

- **Exclusive Criteria**
  1. Patient not willing to participate in clinical trial.
  2. Patient who were suffering from CA of ano rectum, congenital anal stricture, congenital anal stenosis.
  3. Immune compromised patients

WITHDRAWAL CRITERIA FOR STUDY
3. If any adverse effects are noted while conducting clinical criteria, such patients are excluded from study. Subsequent replacement of the patient was done which are not fulfilling the selection criteria.

MATERIALS
a) Formulation composition

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Ingredients (Sanskrit Name)</th>
<th>Ingredients (Latin Name)</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lajjalu</td>
<td>Mimosa pudica</td>
<td>30gm</td>
</tr>
<tr>
<td>2</td>
<td>Nagkeshar</td>
<td>Mesua ferrea</td>
<td>20gm</td>
</tr>
<tr>
<td>3</td>
<td>Lodhra</td>
<td>Symplocos racemose</td>
<td>30gm</td>
</tr>
<tr>
<td>4</td>
<td>Nirgundi</td>
<td>Vitex</td>
<td>20gm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td><em>Bheemseni karpur</em></td>
<td><em>Cinamomum camphora</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10gm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td><em>Yasad bhasma</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5gm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td><em>Tila tail</em></td>
<td><em>Sesamum indicum</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>500ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td><em>Sikhta</em></td>
<td>100gm</td>
<td></td>
</tr>
</tbody>
</table>

**Method of Preparation**

- **Preparation of ointment**

  First of all a *kalka* is prepared with help of all these raw material in given proportion. After that *Tila taila is siddha* by the *kalka*.

  Flame was continued up to *tail siddha lakshnas* like bubbling stopped etc. was observed. *Tail* then filtered using muslin cloth and small pieces of *Siktha* were added. *Karpur* was added in *siddha taila*. Lastly, *yasad bhasma* added. Concept of *kalka* preparation and *taila sidhhi* is taken from the *sharangdhar Samhita*.

  The *tail* was measured and packed in tightly closed containers to protect from light and moisture.

- **Follow up study**

  5th, 10th & 15th days

- **Weight** - one container of *Arshahar malam* containing total 25gm amount of drug.

- **Dose** - 1 gm at one application, twice a day application after defecation in morning and before going to bed at night.

- **Route of Administration** - Local application

  *Fig-(a)* represents: Materials required for preparation of *Arshahar malam*.

  *Fig-(b & c)* represents: During *kalka* preparation & *tila taila*.

  *Fig-(d)* represents: Prepared *Arshaahar malam*.
CRITERIA FOR ASSESSMENT

All the patients selected for the current study were assessed on following parameters during treatment.
1. Bleeding
2. Degree of pile
3. Itching

<table>
<thead>
<tr>
<th>Grades</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No bleeding</td>
</tr>
<tr>
<td>1</td>
<td>Occasional bleeding evident microscopically</td>
</tr>
<tr>
<td>2</td>
<td>Intermittent and evident microscopically</td>
</tr>
<tr>
<td>3</td>
<td>Visible bleeding in the form of splash in the pan</td>
</tr>
</tbody>
</table>

3) Itching

<table>
<thead>
<tr>
<th>Grades</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Absent</td>
</tr>
<tr>
<td>1</td>
<td>Mild (occasionally in a day)</td>
</tr>
<tr>
<td>2</td>
<td>Moderate (intermittent itching)</td>
</tr>
<tr>
<td>3</td>
<td>Severe (continuous itching throughout the day)</td>
</tr>
</tbody>
</table>

RESULT AND OBSERVATION

In this pilot study, total 10 patients were treated with Arshamalhar malam for local application daily for 10 days. All of them have regular follow up. A special case proforma made for clinical study. Separate criteria for assessment were prepared for them. The data collected observed, summarized and results were presented in the form of percentile relief. Following observations were made during the study:

OVERALL PERCENTILE RELIEF ON ALL SYMPTOMS

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Symptoms</th>
<th>Mean BT score</th>
<th>Mean AT score</th>
<th>Mean Difference</th>
<th>Percentile Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bleeding</td>
<td>2.7</td>
<td>0.6</td>
<td>2.1</td>
<td>77.77 %</td>
</tr>
<tr>
<td>2</td>
<td>Degree of pile</td>
<td>1.9</td>
<td>0.9</td>
<td>1.0</td>
<td>52.63 %</td>
</tr>
<tr>
<td>3</td>
<td>Itching</td>
<td>1.5</td>
<td>0.4</td>
<td>1.1</td>
<td>73.33 %</td>
</tr>
</tbody>
</table>

In this study it is found that the signs and symptoms reported by the patients showed significant reduction in Bleeding(77.77%) Degree of pile mass(52.63%) and Itching (73.33%) .there was significant improvement observed in all the parameters like Bleeding, shotha and itching

TOTAL EFFECT IN PERCENTAGE

Total effect of Arshahar malam therapy shows 67.91% relief in all the symptoms of patients enrolled for preliminary study. This shows the effect of Arshahar malam in Arsha with special reference to Haemorrhoids is better.
DISCUSSION

- **Discussion on observation**-
  The objective of the study was to evaluation of *Arshahar malam* in the management of *Arsha*. In this study total 10 patients were registered and treated with *Arshahar malam* per anus for daily 10 days. All the patients having better result from the clinical features i.e. mentioned in assessment criteria has been discuss as follows-

- **Discussion on Total effect of therapy**-
  1. **Bleeding**
     After studying all data thoroughly, in 10 patients of 77.77 % relief was observed from burning sensation.

  2. **Degree of pile**
     In these criteria, in 10 patients of 52.63 % relief was observed from pain.

  3. **Itching**
     In these criteria, in 10 patients of 73.33 % relief was observed from itching.

  4. **Overall effect of therapy**
     In this study above all mentioned criteria it was observed that in 10 patients, 67.91 % patients showed significantly better results of *Arshahara malam* in the management of *Arsha* w.s.r. to haemorrhoids.

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**DISCUSSION ON PROBABLE MODE OF ACTION OF ARSHAHAR MALAM**

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Drug name</th>
<th>Karmukata</th>
<th>Achharya</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><em>Lodhra</em> and <em>Nagkeshara</em></td>
<td><em>Raktastmbhaka</em></td>
<td><em>Hemadri</em></td>
</tr>
<tr>
<td>2</td>
<td>Nirgundi</td>
<td><em>Shothahara</em></td>
<td><em>Bhavprakash</em></td>
</tr>
<tr>
<td>3</td>
<td>Lajjalu</td>
<td><em>Raktastmbhaka</em></td>
<td><em>Bhavprakash</em></td>
</tr>
<tr>
<td>4</td>
<td>Karpura</td>
<td><em>Shoolaghna</em></td>
<td><em>Bhavprakash</em></td>
</tr>
<tr>
<td>5</td>
<td><em>Yasada Bhasma</em></td>
<td><em>Vranaropaka</em></td>
<td><em>Rasratna Samuchhaya</em></td>
</tr>
</tbody>
</table>

So, according this information we can say that content of these ointment effective in *raktastambhna*, *shoothaghna*, *shoolaghana* and *vrana ropana* properties.

In *Arsha vyadhai* patient mainly complain bleeding during or after defeication because engorge arteriovenous plexus with thin or ulcerated mucosal layer erode when patients pass constipated stool. these engorge vein bulge out with submucosal prolapse and seen as thrombosed hemorrhoids.

- *Yasad bhasma* of this ointment containing zinc properties which helps in to strengthen the mucosal layer of anal canal and start healing of mucosal ulcer.

- *Karpura* have anti-inflammatory properties so reduced local inflammation of anal canal.

- *Lodhra lajjalu and nagkeshara have raktastmbhana* properties due to *sthambhana guna* so when we apply ointment active ingredient of these drugs help to reduce bleeding.

- *Nirgundi* work as a *shoothahara* drug so it help to reduce swelling of...
haemorrhoidal mass.

CONCLUSION
As stated in the discussion part, after careful assessment the effect on individual parameters and overall response Arshahar malam seems to be more effective for Arsha i.e. hemorrhoids without any adverse effects.

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